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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,745	11/18/2003	Osman Rathore	VTN 5001CIP	4390

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PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
PERREIRA, MELISSA JEAN	
ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/715,745	RATHORE ET AL.	
	Examiner	Art Unit	
	MELISSA PERREIRA	1618	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 17 July 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1,3-5 and 8-35*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see below.

12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____

13. ☐ Other: _____.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Claims 1,3,4,8-16,19-23 and 25-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimai et al. (JP07-270726A) in view of Christ (US 5,843,186) and further in view of Dziabo et al. (US 5,340,583).

Claims 1,3,4,8-14,16-23,25-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimai et al. (JP07-270726A) in view of Christ (US 5,843,186) and further in view of Tanaka et al. (US 4,139,513).

Claims 1,3,4,8-14,16 and 19-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimai et al. (JP07-270726A) in view of Christ (US 5,843,186) and further in view of Maiden et al. (US 6,367,929B1).

Claims 1,3,4,8-14,16,19,20-23 and 25-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimai et al. (JP07-270726A) in view of Christ (US 5,843,186) and further in view of Nissen et al. (Ophthalmologe 2000, Sept., 97, 640-643; translation).

Claims 1,3,4,8-14,16-23 and 25-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry et al. (EP1050314A1) in view of Tanaka et al. (US 4,139,513).

Claims 1,3,4,8-14,16 and 19-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry et al. (EP1050314A1) in view of Maiden et al. (US 6,367,929B1).

Claims 1-4,8-14,16,19-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry et al. (EP1050314A1) in view of Nissen et al. (Ophthalmologe 2000, Sept., 97, 640-643; translation).

Applicant asserts that Shimai et al. fails to disclose the conditions to test the lenses for antimicrobial actitivy, including the composition of the incubation solution, etc. There is no suggestion in Shimai et al. that antibacterial efficacy was measured at more than one time point. Applicant asserts that Shimai et al. contains no teaching or suggestion on how to make an ophthalmic device which displays the controlled release rate (expressed via a rate constant k) as recited in the present invention.

The instant claims are not drawn to the method of testing antibacterial efficacy or testing lenses for antimicrobial actitivy, including the composition of the incubation solution, etc. Also, the instant claims are not drawn to the method of making the ophthalmic device.

Applicant asserts that Shimai et al. discloses no salt or ligands, and therefore provides no suggestion whatsoever as to how rate constants within the range recited in the present claims could be achieved. Applicant asserts that Shimai et al. fails to disclose how long antimicrobial efficacy lasts, discloses no release rates and contains no data from which release rates could be calculated.

The reference of Shimai et al. was not used to teach of a salt or ligands or to teach of the controlled release contact lens. The reference of Shimai et al. was used to teach of a comfortable contact lens containing silver ions (1 x 1015 ions/cm2 and 1 x 1016 ions/cm2) and a polymer PMMA where there are 0 number of colonies generated. The reference of Christ was used to teach of a contact lens which contains silver and a polymer, such as silicone or PMMA. The silicone polymer of Christ encompasses the polymer of the instant claims. Therefore it would be obvious/predictable to one skilled in the art to substitute the silicone polymer for PMMA in the contact lens of Shimai et al. as there are a finite number of polymer possibilities (see Christ) and the polymers are known to be used for the same device (contact lens). Thus the contact lens of the combined disclosure is capable of the same functions and has the same properties, such as controlled release with the same rate constant. The reference of Dziabo et al. was used to teach of contact lenses where the antimicrobial component, such as silver is covalently bound to the polymeric materials (i.e. polysiloxanes). The antimicrobial component is substantially non-leachable which does convey an amount of leachability. The reactive polymeric material, such as polysiloxanes contains a group/ligand that reacts with the antimicrobial component. The instant claims do not disclose a specific ligand and therefore the ligand of Dziabo et al. encompasses the ligand of the instant claims. Therefore it would be obvious to one skilled in the art to utilize a ligand which reacts with the antimicrobial component to vary the degree of leeching of the controlled release contact lens of the combined disclosures of Shimai et al. and Christ.

Applicant asserts that Christ provides no suggestion as to how desirable silver release rate constant could be achieved in an ophthalmic device and that initial ionized silver concentrations and k values are not disclosed.

Christ teaches of a silicone or PMMA contact lens where the antibacterial agent (i.e. silver) is leechable into the surrounding environment while Shimai et al. teaches that a comfortable contact lens containing silver ions (1 x 1015 ions/cm2 and 1 x 1016 ions/cm2) and PMMA where there are 0 number of colonies generated. Therefore it would be obvious/predictable to one skilled in the art to substitute the silicone polymer for PMMA in the contact lens of Shimai et al. as there are a finite number of polymer possibilities (see Christ) and the polymers are known to be used for the same device (contact lens). The silicone polymer of Christ encompasses the polymer of the instant claims. It would also be obvious to one skilled in the art to utilize the polymer of Christ for the contact lenses of Shimai et al. which contains silver ions (1 x 1015 ions/cm2 and 1 x 1016 ions/cm2) and thus leech the silver in a controlled manner to generate zero bacterial colonies.

Applicant asserts that the references are absolutely silent as to the potential risk of argyria.

The contact lens of the combined disclosures encompass those of the instant claims and therefore are capable of the same functions (i.e. do not cause argyria) and have the same properties.

Applicant asserts that Tanaka et al. or Maiden et al. do not disclose antimicrobial compounds.

The references of Tanaka et al. and Maiden et al. were not used to teach of an antimicrobial compound but used to teach of continuously worn contact lenses and contact lenses comprising hydrogel materials, such as Balafilcon A, respectively.

Applicant asserts that Nissen et al. does not disclose any information relating to the form of silver on the lens, the

concentration of silver on the lenses, the method by which the silver layer was applied or released from the lens.

The instant claims are not drawn to the method of making the contact lens. The reference of Nissen et al. teaches that the silver is present in traces on the lenses and in the concentration range of 50-500 □g/L and in combination with the controlled release contact lens of the combined disclosures of Shimai et al. and Christ it would have been obvious to form of silver ion to utilize for the lense.

Applicant asserts that Barry et al. does not provide guidance as to the initial silver concentration , 0.01ppm to 25ppm, which is below the range recited in the present claims.

The instant claims recite, about 50ppm to about 3000ppm. Therefore 25ppm encompasses about 50ppm as the term about is not defined.

The amendment to the specification is acknowledged and accepted.

The objection to the drawings is withdrawn.